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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,558	01/03/2002	Thierry Crost	02508.0092	2328

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EXAMINER	
MENON, KRISHNAN S	
ART UNIT	**PAPER NUMBER**
1723	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,558	CROST ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-20 and 23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-20 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 15-20 and 23-29 are pending after the amendment of 9/2/05.

Double Patenting

Applicant is advised that should claim 20 be found allowable, claim 28 depending from claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-20 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,010,475) in view of Scholander et al (US 5,840,190).

Process claims 15-20 and 23-29: Thomas in view of Scholander teach the process as claimed, details of which are given under each claim below. The actual process steps in the teaching of Thomas in view of Scholander may not be in the same exact sequence as claimed. However, Selecting or changing order of process step is

prima facie obvious. Ex parte Rubin , 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Claims 15 and 26: Thomas teaches a method of preparing a flat or hollow fiber membrane of acrylonitrile with anionic groups (see Thomas col 5 lines 1-53 and examples), fitting the membrane or bundle of hollow fibers in a case (see figures), preparing the cationic polymer solution of cationic polymer large enough not to pass through the membrane (col 6 lines 45-55), bringing the solution in contact with the membrane, and then purging the solution of cationic polymer. Claims 15 and 26 differ from the teaching of the Thomas reference in the limitation of reducing the thrombogenic character of the membrane by coating the membrane with an anticoagulant having anionic groups that form ionic bonds with the cationic groups of the first coated layer. Scholander teaches coating heparin on the membrane, heparin binds ionically with amino-groups on the surface – see col 5 lines 30-67, and examples. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Scholander in the teaching of Thomas to have biocompatible membranes,

especially in extracorporeal blood circulation, as taught by Scholander. One would use Scholander's teaching to modify the teaching of Thomas especially because of the advantages described in col 1 line 10 – col 2 line 3.

Claim 26 has the further added limitation of "sterilizing the exchanger when the semipermeable membrane ... is coated with the cationic polymer and the anticoagulant agent". This recitation would mean that the sterilization could be done during or after coating with cationic polymer and anticoagulant. Thomas teaches coating with cationic polymer and simultaneously sterilizing in column 7 lines 53-67. Thomas also teaches sterilizing the membrane with ethylene oxide after coating with PEI in column 8 lines 34-51. It may be noted that the steps of sterilizing after coating with PEI is described by Thomas as less desirable. However, "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments" (In re *Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)).

Claims 16 and 17: the rinsing of the membrane to remove the excess cationic polymer or the anticoagulant is taught by the references – example 1 of Scholander and col 5 lines 48-51 of Thomas.

Claims 18 and 19: sterilization when coating with the anticoagulating agent: Thomas in view of Scholander teaches sterilization – see Thomas example 1 or col 6 lines 55-60 or col 5 lines 44-47, or column 8 lines 34-51.

Claims 23 and 24: sterilization with gamma ray or ethylene oxide – see example 1 or col 6 lines 55-60 or col 5 lines 44-47of Thomas.

Claim 25: Thomas in view of Scholander also teaches the method of preparing a composite semipermeable membrane by the steps of coating a semipermeable support base layer (col 5 lines 1-65 of Thomas, example 1 of Scholander), coating the cationic polymer solution, and then coating the anticoagulant solution.

Claims 20 and 28: Method wherein the cationic polymer prepared by ultrafiltration to exclude chains capable of passing through the semipermeable membrane – Thomas in view of Scholander does not teach this step of the process. However, Thomas teaches using polymer of molecular weight (or size) large enough that it does not enter the pores – see col 6 lines 45-55. The step of purifying the cationic polymer is not required since it starts with the purified polymer, or polymer of the required molecular weight. (Omission of an element and its function is obvious if the function of the element is not desired: Ex parte Wu , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989))

Claim 27: cationic polymer is polyethyleneimine at 1-30 mg/m2: Thomas teaches 10 mg in 1.44 m2, which meets the claim.

Claim 29: anticoagulant is heparin, coated in µg/sq.cm given in the examples of Scholander, are equivalent in range to the 200-20,000 IU/m2.

Response to Arguments

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive.

Applicant's arguments are, for the most part, directed at claim 26, and particularly, at the limitation of the sterilization step in claim 26. These arguments are not persuasive because (1) Thomas does teach sterilization ***when*** coating the PEI, and also sterilization after coating the PEI as shown in the rejection. The coating of the anticoagulant is taught by the secondary reference.

Applicant's further arguments are directed at the motivation to combine the references, because Thomas and Scholander allegedly teach away from one another. This is also not persuasive because (1) column 3 lines 38-40 of Thomas teaches that sterilization is done after the surface is modified, (2) column 5 lines 57-63 teaches sterilizing ***when*** coating with the substance, as claimed (substance dissolves and circulates to coat with the sterilizing solution), (3) Scholander is used only for the teaching of the anticoagulant, (4) Thomas also teaches coating the cationic polymer before sterilizing, as explained in the rejection. Therefore, there is "no teaching away from each-other" in the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERRY K. CECIL
PRIMARY EXAMINER

Krishnan S. Menon
Patent Examiner
10/5/05